REMARKS

The 35 U.S.C. §112, second paragraph rejections

Claim 1 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. This rejection is respectfully traversed.

The Examiner states that in lines 11-12 of claim 1, the metes and bounds of the phrase "heat shock response elements (-260 to 30) of the human heat shock 70 gene promoter" are unclear, and requests clarification.

In response, Applicant respectfully submits that claim 1 has been amended to clarify that the heat shock response elements referred to in the claim consist of the nucleotide sequence –260 to 30 of the human heat shock 70 gene promoter. The specification refers to this sequence on page 11, lines 16-18, in describing the elements of the pDATH-X vector shown in Figure 1A, and to **Voellmy R.**, *et al.*, (*Proc. Natl. Acad. Sci. USA* 82: 4949-4953 (1985)). Given this information, one skilled in the art would easily recognize the precise nucleotide sequence described.

Additionally, the Examiner states that the meaning of the term "complementary sequence" in lines 3-4 of claim 1 is unclear, and that deleting "sequence" might be remedial. According to the Examiner's suggestion, Applicant has amended claim 1 to delete "sequence" to clarify the meaning of the claim.

Accordingly, Applicant respectfully requests that the rejection of claim 1 under 35 U.S.C. §112, second paragraph, be withdrawn.

The Specification Objection and Claim Rejection under 35 U.S.C. §112, first paragraph

The Examiner states that the application does not comply with the rules for the deposit of biological material, so that the specification is objected to under 35 U.S.C. §112, first paragraph as failing to provide an enabling disclosure for the claimed invention. The Examiner states that the enablement requirements for the specification and claim 1 may be satisfied by a deposit of pDATH-X.

Applicant hereby submits that a pDATH-TNFα vector (designated as PTA-4083) has been deposited at American Type Culture Collection. The plasmid pDATH-TNFα is an example of pDATH-X and carries all the disclosed features of pDATH-X. Applicant further submits that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon granting of a patent. Accordingly, Applicant submits that the deposit overcomes the objection to the specification and the rejection of claim 1 under 35 U.S.C. §112, first paragraph. Applicant respectfully requests that the rejection be withdrawn.

This is intended to be a complete response to the Office Action mailed April 22, 2003. If any issues remain outstanding, the Examiner is respectfully requested to telephone the undersigned attorney of record for immediate resolution.

Respectfully submitted,

Date: June 13, 2003

Benjamin Aaron Adler, Ph.D.,J.D.
Registration No. 35,423
Counsel for Applicant

ADLER & ASSOCIATES
8011 Candle Lane
Houston, Texas 77071
(713) 270-5391 (tel.)
(713) 270-5361 (facs.)
badler1@houston.rr.com

ATCC

10801 University Blvd • Manassas, VA 20110-2209 • Telephone: 703-365-2700 • FAX: 703-365-2745

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF
THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

Children's Hospital Los Angeles
Attn: Yuen Kai Fung, Ph.D
2455 Ivanhoe
Los Angeles, CA 90039

Deposited on Behalf of: Clayton Foundation for Research

Identification Reference by Depositor:	**Patent Deposit Designation**
Plasmid: pDATH-TNFα	PTA-4053

The deposit was accompanied by: __ a scientific description _ a proposed taxonomic description indicated above.

The deposit was received February 15, 2002 **by this International Depository Authority and has been accepted.**

AT YOUR REQUEST: X **We will inform you of requests for the strain for 30 years.**

The strain will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strain, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strain.

If the culture should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace it with living culture of the same.

The strain will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the culture cited above was tested February 28, 2002. **On that date, the culture was viable.**

International Depository Authority: American Type Culture Collection, Manassas, VA 20110-2209 USA.

Signature of person having authority to represent ATCC:

Marie Harris

Date: March 18, 2002

Marie Harris, Patent Specialist, ATCC Patent Depository

cc: Dr. Benjamin Adler
(Ref. Docket or Case No. D0783)